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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/622,892

07/16/2003

Shyh-Chyi Kuo

64,600-117

2760

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7590

05/16/2006

AKIN GUMP STRAUSS HAUER & FELD L.L.P.
ONE COMMERCE SQUARE
2005 MARKET STREET, SUITE 2200
PHILADELPHIA, PA 19103

EXAMINER

ARANCIBIA, MAUREEN GRAMAGLIA

ART UNIT

PAPER NUMBER

1763

DATE MAILED: 05/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/622,892

Applicant(s)

KUO ET AL.

Examiner

Maureen G. Arancibia

Art Unit

1763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 2-12 and 16-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 13-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 July 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Species D in the reply filed on 21 February 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. The Examiner notes Applicant's identification of Claims 13-16 as readable on the elected species. However, Claim 16 is actually readable on non-elected Species E, wherein repeated steps of depositing and imaging photoresist layers results in a flow passage with a variable diameter for serving a storage function. (See Figures 5A-5G) Accordingly, Claim 16 will not be examined with the elected species.
3. In the reply filed on 21 February 2006, Applicant did traverse the Examiner's position that no claims are fully generic. Applicant argues that Claim 1 is believed to be generic to all species, since each of the five steps in Claim 1 is performed in each of the six species identified by the Examiner. The Examiner agrees that Claim 1 is readable at least on elected Species D, and Claim 1 will be examined on the merits. However, it appears that Claim 1 is not fully generic, since it appears that while Claim 1 may be generic to Species A, B, D, E, and F, the steps recited in Claim 1 do not appear to be performed in Species C. (See Figures 3A-3C)
4. Claims 2-12 and 16-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic

or linking claim. Election was made **without** traverse in the reply filed on 21 February 2006.

Drawings

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: **200** (Line 2 on Page 14); **202** (Line 2 on Page 14); **606** (Line 9 on Page 19). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

6. The use of the trademark TEFLON has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 6,551,849 to Kenney.

Kenney teaches a method for fabricating a hollow micro-needle array (Column 3, Lines 55-56; Column 8, Lines 11-12), comprising the steps of providing a silicon substrate 10 (Figure 1A); depositing a protective layer 30 (*photoresist*) on said silicon substrate (Figure 1B); defining a plurality of regions (*pattern 40*) for wet etching (Figure 1C); wet etching said silicon substrate (Column 7, Lines 7-17) forming a plurality of recesses 80 having inclined sidewalls, as broadly recited in the claim (Figure 1E); and continuing processing said plurality of recesses forming a hollow micro-needle array (Column 7, Line 19 - Column 8, Line 50). (See Column 3, Lines 55-67; Column 6, Line 16 - Column 8, Line 50.)

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kenney in view of U.S. Patent 6,663,820 to Arais et al. U.S. Patent 6,703,297 to Hellig is cited as evidence regarding silicon nitride coating.

In regards to Claim 13, Kenney teaches a method for fabricating a micro-needle array comprising the steps of providing a silicon substrate 10 (Figure 1A); depositing a protective layer 30 (*photoresist*) on said silicon substrate (Figure 1B); defining a plurality of regions (*pattern 40*) for wet etching (Figure 1C); and wet etching the plurality of wet etch regions on said silicon substrate (Column 7, Lines 7-17) forming a plurality of recesses 80 having inclined sidewalls, as broadly recited in the claim (Figure 1E).

Kenney further teaches depositing sequentially an anti-reflective coating layer (*silicon nitride layer 90'*) and a sacrificial layer (*thin layer of polycrystalline silicon 100*) on top of said silicon substrate (Figures 1F and 1G); filling the recesses 80 with tungsten 110 (Column 8, Lines 9-11); patterning the bottom surface 150 of the silicon substrate 10 using standard photolithography (Column 8, Lines 23-24); and removing the bulk of silicon substrate 10, the anti-reflective coating layer 90', and the sacrificial layer 100 to obtain a bottom layer with inclined sidewalls (Figure 1L; Column 8, Lines 25-48), as broadly recited in the claim.

The silicon nitride layer 90' would inherently have anti-reflective properties, and thus meets the recited limitation of an anti-reflective coating layer. Hellig is cited as evidence that silicon nitride is a known anti-reflective material. (Column 1, Lines 56-57) When a rejection is based on inherency, a rejection under 35 U.S.C. 102 or U.S.C. 103 is appropriate. (See *In re Fitzgerald* 205 USPQ 594 or MPEP 2112).

The polycrystalline silicon layer 100 meets the recited limitation of a sacrificial layer, since it is removed in order to expose the conductive micro-needles. (Column 8, Lines 43-47)

In regards to Claim 13, Kenney does not expressly teach that the step of patterning the bottom surface 150 of the silicon substrate 10 using standard photolithography comprises the steps of depositing a photoresist layer and imaging said photoresist layer for the micro-needle array.

However, Kenney further teaches a standard (*conventional*) photolithography process comprising the steps of depositing a photoresist and imaging (*patterning*) said photoresist, as broadly recited in the claim. (Column 10, Lines 41-43)

It would have been obvious to one of ordinary skill in the art to use the same steps taught by Kenney as comprising a standard photolithography process in patterning the bottom surface of the silicon substrate. The motivation for doing so, as would have come from the teachings of Kenney or from the knowledge of one of ordinary skill in the art, would have been to protect any portion of the silicon substrate not desired to be etched (such as an area surrounding the micro-needle array) or to retard etching of the silicon substrate in a vertical line with the micro-needles themselves, so as to protect the micro-needles from being damaged by the etchant.

The step of imaging the photoresist layer in the modification of Kenney just discussed meets the limitation of being "for said micro-needle array," as broadly recited in the claim, since this step is part of the process of fabricating the micro-needle array.

In regards to Claims 13 and 14, Kenney does not expressly teach that the method further comprises the step of, after the steps discussed above of depositing of the photoresist layer and removing of the sacrificial layer, imaging and developing the bottom layer comprising the solid (tungsten) micro-needle points to form a hollow micro-needle array.

Arais et al. teaches that holes can be burned through solid micro-needle points by laser ablation to form hollow micro-needles. (Column 13, Lines 35-40) This process is considered to meet the broadly recited limitation in the claims of "imaging and developing the bottom layer," since radiation is used (which meets the broad recitation of imaging) and holes are formed (which meets the broad recitation of developing).

It would have been obvious to one of ordinary skill in the art to modify the method taught by Kenney to include the step of, after the steps discussed above of depositing of the photoresist layer and removing of the sacrificial layer, imaging and developing the bottom layer by burning holes through the solid micro-needle points by laser ablation to form a hollow micro-needle array, as taught by Arais et al. The motivation for making such a modification would have been to use an art-recognized equivalent method of forming hollow micro-needles by converting solid micro-needle points after fabrication to hollow micro-needles, as taught by Arais et al., instead of forming hollow micro-needles by coating only a thin layer of the needle-forming material in the recesses formed in the silicon substrate, as taught by Kenney (Column 8, Lines 6-50).

In regards to Claim 15, the sacrificial layer 100 taught by Kenney meets the broad recitation of a mold release layer, since it defines the molded micro-needle

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material 110 from the mold recess 80, and its removal represents the release of the micro-needle tips from the mold recesses 80. (Column 8, Lines 6-11 and 43-47)

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen G. Arancibia whose telephone number is (571) 272-1219. The examiner can normally be reached on core hours of 10-5, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Parviz Hassanzadeh can be reached on (571) 272-1435. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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